Guidelines For The Investigation & Control of Food, Drug & Other Consumer Product Complaints

California Department of Health Services
Division of Food, Drug, and Radiation Safety
Food and Drug Branch

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About This Manual

The Healthy People Year 2010 Objectives, adopted by the Department of Health Services (DHS) for "healthy people in healthy communities" represents a comprehensive, promotion and disease prevention agenda and is designed to improving the health of all Californians, calling for cooperative efforts by local, state and federal health regulatory agencies. As part of this vision, the Food and Drug Branch (FDB) within DHS's Division of Food, Drug and Radiation Safety has developed a statewide procedure manual for handling consumer complaints. The manual is recommended for use by local health departments and local environmental health agencies to coordinate complaint investigations to identify product problems, ensure all contaminated or defective products are removed from commerce, and jointly develop prevention and control measures.

The earliest edition of DHS's consumer complaint manual was issued in 1972 by the Bureau of Food and Drug --- Informational Circular F&D 72-7: *Recommended Procedure for the Investigation of Consumer Complaints Relative to Foods*. It described the classifications of complaints prioritized to effectively coordinate consumer complaints and sample collections between local health departments and the State Department of Public Health. In 1987, FDB revised the protocol and developed a document entitled: *Policy and Procedures for the Management of Consumer Product Complaints, Consumer Product Tampering Incidents, and Removal of Consumer Products from the Marketplace*. The revised document was compiled in response to requests by County Environmental Health Directors and Local Health Officers for guidelines for handling consumer complaints pertaining to foods, drugs, medical devices, cosmetics, tableware and hazardous household products.

In recent years, our experiences with a few notable disease outbreaks have demonstrated the need to improve the speed and effectiveness of investigations and collaborations among various federal, state and local health agencies. This led to the establishment of an FDB review team to re-evaluate the 1987 document. With the Healthy People Year 2010 Objectives as a guide, the team has revised the original documents and produced *Guidelines for Investigation and Control of Food, Drug and other Consumer Product Complaints*.

This document was completed with the assistance and advice of many colleagues within the California Department of Health Services, local health departments, local environmental health agencies, the California Department of Food and Agriculture, the U.S. Food and Drug Administration, the California Environmental Protection Agency, and the staff of FDB. Their contributions are gratefully acknowledged.
It is FDB's hope that this document will be distributed to all persons involved in regulating consumer products to effectively coordinate future emergency responses in the State of California.

James M. Waddell, Chief
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Please FAX any corrections or suggested improvements to this manual to us at (916) 322-6326. If you would like extra copies of this manual, please call (916) 445-2264 or forward a computer disk to:

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Introduction

Purpose

This document was developed as a guideline to assure the effective investigation of food, drug and other consumer product complaints and tampering incidents through the coordinated efforts of state and local health agencies. It describes the cooperative relationship between local health departments (LHDs), the California Department of Health Services (DHS) and other agencies for the prompt investigation and control of consumer product complaints and tampering incidents, and for the removal of unsafe consumer products from the marketplace. It describes agency responsibilities and provides guidelines for agency cooperation to assure an effective response without duplication of efforts.

Product Definition

"Consumer product" means any food, drug, medical device, cosmetic, tableware or hazardous substance as defined by Sections (§§) 109935, 1099225, 109920, 109900, 1088555, and 108125 of the California Health and Safety Code (HSC). Consumer products also include art and craft materials, herbal products and folk remedies.

Complaint Investigation and Follow Up

Initial Epidemiologic Investigation

Complaints involving illness or injury must be investigated to determine the nature of the illness or injury and whether a consumer product might be a causal factor. For example, when there is a possible foodborne illness, the investigation would attempt to identify the cause of illness (e.g., chemical or microbiological contaminant) and the specific product involved.

Follow Up Investigation & Risk Management

When the initial epidemiological investigation finds that a consumer product is the likely cause of the illness or injury, a follow-up investigation is conducted. For example, when a pathogenic microorganism is found to cause a foodborne illness, the follow-up investigation is conducted to determine the source of the contamination (e.g., mishandling by the consumer, poor restaurant sanitation, manufacturing error by a commercial food processor) and the scope of the problem (e.g., individuals in a particular family, only persons eating at a specific restaurant, or everyone eating a particular commercially processed food). Once this is determined, appropriate risk management steps can be taken to protect those individuals who may be exposed to the contaminated product. Risk management actions may include removal of products from the

marketplace (See Chapter 5), halting production at a restaurant or commercial food processor until the source of the contamination is corrected, and warning affected individuals by direct contact or through the media (e.g., press release).

The roles of state and local health agencies in the investigation and follow-up of complaints involving illness or injury vary according to the type of products involved. Table 1 illustrates agency responsibilities for illness and injury investigations involving various consumer products. The agencies most likely to be involved are listed but there may be other state and local agencies involved as well. For example, the county coroner or medical examiner may become aware of consumer product problems and assist with the initial and follow-up investigations.

Agencies Responsible For Complaint Investigation & Follow Up

Note: Appendix B is a list of agencies, contact persons and telephone numbers.

Local Health Departments (LHDs)

For this document, LHDs include all city or county public health and environmental health agencies that may be involved in the investigation and control of consumer product complaints and tampering incidents. In certain counties, environmental health departments are separate from public health departments and have responsibilities for regulating foods sold at retail and enforcing the California Uniform Retail Food Facilities Law. These Comprehensive Environmental Health Agencies are identified in Appendix B. Regardless of organizational structure, it is essential for LHDs to assure communication and cooperation between environmental health and epidemiological investigation and laboratory staff.

California Department of Health Services (DHS)

The Division of Food, Drug, and Radiation Safety (DFDRS) mission is to protect and improve the health of all California residents by assuring the safety of foods, drugs, medical devices, and radiation, and the effectiveness of drugs and medical devices, through investigation, inspection, and control of the sources of these products.

> **The Food and Drug Branch (FDB)** is the regulatory agency within DFDRS responsible for assuring the safety of consumer products sold in California. FDB is authorized to investigate consumer product complaints and tampering incidents, and to initiate corrective action including removal of unsafe products from the marketplace.
>
> **The Food and Drug Laboratory Branch (FDLB)** within DFDRS provides laboratory analytical and consultative support for the enforcement of the state laws and regulations that ensure the safety and quality of consumer products in California. The FDLB analyzes FDB submitted food and drug samples to determine their chemical, physical, nutritional or toxicological properties, identify microbial and chemical contamination and assure these products are safe for human consumption.

The Division of Communicable Disease Control (DCDC) conducts surveillance, investigation, and control programs for communicable diseases in California. The *Disease Investigation and Surveillance Branch* (DISB) provides expert consultation and assistance for epidemiologic investigation of communicable disease outbreaks in the state. In the event of a foodborne disease outbreak due to foods of commercial origin, both the *Disease Investigations Section* coordinates with FDB in conducting the investigation. In addition, DCDC reviews reports of epidemiologic investigations of foodborne disease outbreaks associated with microbial agents and chemical intoxications that are reported by LHDs.

The Microbial Diseases Laboratory Branch (MDLB) performs microbiological examinations to aid in the definitive diagnosis and control of infectious disease agents. The *Environmental Microbial Diseases Section* (EMDS) within the MDLB conducts microbiological analyses of FDB submitted samples of consumer products to determine their safety and quality. MDLB also provides consultative services to the LHD laboratories or others when requested

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The Division of Environmental and Occupational Disease Control (DEODC), *Environmental Health Investigations Branch* (EHIB) identifies and measures the occurrence of diseases that are potentially related to chemical exposures (i.e., pesticide poisoning) or toxic substances in the environment. DEODC focuses on the prevention and control of these diseases, coordinating with FDB when needed.

The Office of Public Affairs (OPA) coordinates with the above agencies in preparing official press releases and public communications on health risks to consumers regarding unsafe consumer products in the marketplace and to announce remove-from-sale orders or product recalls.

California Department of Food and Agriculture (CDFA)

CDFA regulates raw agricultural commodities (i.e., fresh uncut fruits and vegetables), milk and dairy products and processing of meat and poultry products at retail.

The Milk and Dairy Foods Control Branch (MDFCB) regulates the production, processing and sale of milk and dairy products and products resembling milk products in California. MDFCB becomes involved in an investigation of illness when MDFCB regulated products are implicated. Recently, a MOU was established between DHS and CDFA defining a protocol to be followed after the isolation of human pathogens from raw milk. The MOU addresses any milkborne pathogen though, historically, the pathogen of primary concern has been *Salmonella*. When a suspect human pathogen is isolated, the isolating laboratory notifies MDFCB. MDFCB then notifies the dairy from whose product the suspect isolate was made, the county medical milk commission responsible for certification of the involved milk products (if the isolate is from a certified milk or milk product), DCDC and FDB. MDFCB then determines the "quality assurance dates" ("pull dates") and herd codes for each product which may be affected in the event the suspect isolate is confirmed, and notifies DCDC and FDB. MDFCB notifies all parties previously notified when the isolate is confirmed. CDFA is responsible for determining what regulatory action shall be taken upon confirmation. These actions may include ordering the affected dairy to stop distribution of raw milk and raw milk products from the affected source of milk, and ordering remove-from-sale of the raw milk and raw milk products. When CDFA determines that a recall order must be issued, it will notify the affected dairy to begin recalling the products, and ask the DHS Director to order LHDs to verify the recall. In addition, DHS will issue a press release warning consumers of the hazard.

The Meat and Poultry Inspection Branch (MPIB) is responsible for inspecting meat and poultry products which are exempt from federal inspection by the USDA. Examples of those products include game birds, rabbits, sausages and cured and smoked meats prepared at retail meat markets.

The Fruits and Vegetables Standardization Branch (FVSB) regulates the quality standards of produce (fruits and vegetables) in its raw natural state including organic produce. Examples of quality characteristics regulated include insect injury, mold, physical damage (sun, freezing, hail, bruising, etc.), growth cracks, internal and external coloration, etc.

The Animal Health Branch (AHB) is the State's veterinary medical unit that protects consumers, livestock populations and California's economy from catastrophic animal diseases. The AHB implements programs which protect California's consumers and livestock industries; and ensures the availability, affordability, and wholesomeness of food of animal origin. In addition, AHB prevents transmission of potential pathogens to humans by facilitating preharvest food safety and quality assurance programs with industry; and serves as a liaison to improve education and communications between the public, industry, and government agencies in programs affecting animal health and the safety of food consumed by humans.

California Environmental Protection Agency (CAL-EPA)

The Department of Pesticide Regulation (DPR) regulates pesticide use in California. The *Pesticide Enforcement Branch* monitors pesticide levels in foreign and domestic produce, and may seize produce bearing excessive or unapproved pesticide residues. It contracts with CDFA's *Chemistry Services Laboratory* to perform pesticide residue analyses of produce. The laboratory may analyze samples when consumer illness is linked to pesticides in domestic and imported raw fruit or vegetables.

The Office of Environmental Health Hazard Assessment (OEHHA) provides consultation for decision making about various regulatory actions concerning chemical contaminants. In particular, OEHHA's *Pesticide and Environmental Toxicology Section* is interested in illnesses that may be related to pesticides or other toxic chemicals.

U.S. Food and Drug Administration (FDA)

FDA shares with FDB jurisdiction over foods, drugs, medical devices, tableware, and cosmetics sold in California when there is interstate commerce. FDA works with FDB in handling consumer product incidents involving products produced or distributed out-of-state.

U.S. Department of Agriculture (USDA)

USDA shares with FDB and CDFA jurisdiction over meat and poultry products. USDA regulates the slaughter and processing of red meats and poultry products.

U.S. Consumer Product Safety Commission (CPSC)

CPSC shares with FDB jurisdiction over hazardous substances and related consumer products.

Federal Bureau of Investigation (FBI)

The FBI shares with FDB the investigation of tampering, extortion, and related crimes when consumer products are involved.

Local law enforcement agencies (PD)

PDs include police departments and sheriff offices.

Table 1 - Agency Responsibilities in Illness/Injury Investigations

PRODUCT	LEAD AGENCY FOR INITIAL/EPI INVESTIGATION	LEAD AGENCY FOR F/U INVESTIGATION AND RISK MANAGEMENT
All Tampering	FDB/ FDA	FDB
Non-Food (e.g., drug, medical device)	FDB/ FDA	FDB
Commercially Processed Foods	LHDs	FDB
Noncommercially Processed Foods	LHDs	LHDs
Produce (pesticide related illness)	LHDs	DPR
Produce (non-pesticide related illness)	LHDs	FDB
Dairy Products Produced out-of-state	LHDs	FDB, FDA
Dairy Products Produced in California	LHDs	CDFA, FDA, DCDC
Meat & Poultry	LHDs	CDFA, USDA, DCDC
Shell Eggs	LHDs	CDFA, USDA, FDB, DCDC
Seafood & Shellfish	LHDs	FDB

CDFA	California Department of Food and Agriculture	DCDC	DHS' Division of Communicable Disease Control
DEODC	DHS' Division of Environmental & Occupational Disease Control	DPR	Department of Pesticide Regulation
FBI	Federal Bureau of Investigation	FDB	DHS' Food and Drug Branch
FDLB	DHS' Food and Drug Laboratory Branch	LHDs	Local Health Departments
MDLB	DHS' Microbial Diseases Laboratory Branch	OEHHA	CAL-EPA Office of Environmental Health Hazard Assessment
PD	Police Department	FDA	U.S. Food and Drug Administration
USDA	U.S. Department of Agriculture		

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Consumer Product Complaint Investigation Protocol

Background

DHS and the LHDs are responsible for investigating consumer product complaints in a timely manner, and assuring appropriate follow-up investigation and control actions. Consumer complaints may be an indicator of product problems which, without appropriate follow-up, could pose a significant risk to public health. FDB has primary responsibility for the safety of consumer products in California, but the cooperation of many agencies is necessary for effective complaint investigation and follow-up. This protocol identifies agency responsibilities and provides guidance for effectively responding to consumer product complaints.

LHD/DHS Interaction

Non-food Consumer Product Complaints

FDB is responsible for the initial investigation of all non-food consumer product (drug, medical device, cosmetic, hazardous household product) complaints. LHDs are to notify FDB of all non-food consumer product complaints. FDB recommends that the *Consumer Product Complaint Investigation Form* included in Appendix B be used as a guide when referring complaint information to FDB. FDB will conduct the initial investigation and coordinate risk management and control activities. FDB may contact the LHDs for assistance if additional resources are needed to protect the public health (See Chapter 4).

Food Product Complaints

Food Complaints Not Involving Illness or Injury

The LHD is responsible for the investigation of complaints about foods served or sold at retail food facilities that do not involve illness or injury (e.g., cockroach in food served at a restaurant, filth in bulk food bins at a market). All other food complaints not involving an illness or injury (e.g., swollen cans of tomato sauce, a cupcake with metal fragments in it or "foul" tasting produce) should be referred to FDB for follow-up (see Appendix B). FDB recommends that the *Consumer Product Complaint Investigation Form* be used as a guide for referring complaint information to FDB.

Food Complaints Involving Illness or Injury

Suspected Botulism The LHD is to report all cases of suspected botulism to DHS immediately by telephone (24-hour emergency number: (510) 540-2308).

The LHD is to conduct the initial epidemiological investigation of complaints involving human illness or injury to determine if the illness is foodborne, and what food is implicated. DHS will provide assistance with the investigation upon LHD request. FDB can provide technical consultation and assistance in the evaluation of food processing, holding and handling practices, food safety, and inspection and sampling methods. DEODC and DCDC can provide consultation and assistance for epidemiological investigations. The DHS laboratories (MDLB and FDLB) can provide consultation and assistance for analytical methods, sampling requirements and sample analysis.

Commercially Processed Foods, Meat or Poultry Products, Dairy Products, or Produce As soon as the LHD investigation implicates a commercially processed food, a meat or poultry product, a dairy product or produce (i.e., the problem does not appear to be due to mishandling or contamination at the retail food facility or by the consumer), the LHD should immediately alert FDB and DCDC. FDB recommends that the *Consumer Product Complaint Investigation Form* be used as a guide when providing alert information to FDB. It is important for FDB to be alerted as soon as possible so they can notify appropriate state and federal agencies, and plan follow-up investigation and risk management.

In most cases, the lead agency for follow-up investigation and risk management will be FDB, although DPR is the lead agency for follow-up and risk management when there are pesticide-related illnesses involving produce, CDFA is the lead when there are illnesses involving dairy products produced in California, FDA is the lead when there are illnesses involving dairy products produced outside of California, and USDA or CDFA is the lead when the illness involves meat, or poultry. There may be additional agencies (including LHDs - see Chapter 4) involved in follow-up investigation and risk management depending on the products involved and the extent of the problem. Illnesses involving shell eggs are investigated in accordance with California Egg Quality Assurance Plan. LHD's should notify FDB immediately when shell eggs are implicated, and FDB will coordinate investigation with appropriate agencies.

Once the LHD investigation is completed, the *Investigation of a Foodborne Outbreak Form* (Appendix B) should be completed and forwarded to DCDC. **Completion of this form is extremely important for the tracking of foodborne diseases in California, and should be given a high priority.** Pesticide related illnesses require additional reporting. Please refer to the discussion of reporting forms in Appendix A for more information.

Note: When a LHD develops its protocol for the investigation of consumer illness complaints, DHS recommends that the IAMFES (International Association of Milk, Food and Environmental Sanitarians, Inc.) publications be used for guidance. The IAMFES publications are excellent references for conducting foodborne and waterborne illness investigations. Copies of these publications [Procedures to Investigate Foodborne Illness 4th Edition, 1987 (revised 1988) or Procedures to Investigate Waterborne Illness, 1st Edition, 1979] can be obtained by contacting IAMFES at 200 W Merle Hay Centre, 6200 Aurora Ave., Des Moines, IA 50322. Phone number: 515-276-3344, FAX: 515-276-8655.

Laboratory Testing

The LHD is responsible for collecting any samples necessary for its initial investigation. All samples collected are to be submitted to the LHD's laboratory for analysis. The DHS laboratories may be consulted for information on sample collection and analysis, and the LHD may submit samples to the DHS laboratories for testing when necessary. The specific DHS laboratory whose assistance is required is to be consulted before any samples are sent, and sample submission coordinated with the FDB Administrator or appropriate Section Chief. Only the LHD laboratory, the local health officer or designee may authorize submission of samples to the DHS laboratories. Samples to be analyzed by the DHS laboratories should not be submitted directly to the FDB offices without prior authorization of the FDB Administrator or Section Chief.

A consumer may not submit a sample to the DHS laboratories for his/her personal information. But if a consumer requests a laboratory analysis and a human illness is involved, the LHD should collect all samples necessary for its investigation. If a human illness is not involved, consumers requesting analyses should be referred to a private laboratory. In circumstances where the product is a commercially processed food and the FDB Administrator or Section Chief believes that analysis of the sample will yield valuable public health information, FDB may request the

DHS laboratories to perform the analysis. A form for submission of samples to the DHS laboratories is included in Appendix A.

FDB Investigation Of Complaints

Consumer complaints received by FDB directly or when referred from other agencies, are entered into an FDB internal database system and recorded on the Consumer Product Complaint Investigation Form (Appendix A). FDB classifies consumer product complaints and tampering incidents according to their health significance:

Class I (emergency)

This category includes any incident which presents, or may reasonably be expected to present: (a) serious adverse health consequences including a threat to life, a necessity for immediate medical or surgical intervention by professional medical or health personnel or permanent damage or impairment of a body structure or function; or (b) other adverse health consequences where significant numbers of people are or may be expected to be at risk (e.g., botulism, paralytic shellfish poisoning, or product tampering).

Class II (urgent)

This category includes any incident which presents, or may reasonably be expected to present, other adverse health consequences which are of a temporary or medically reversible nature. (Example: finding a foreign object in a food product.)

Class III (other)

This category includes any incident which presents, or may reasonably be expected to present, no adverse health consequences. (Examples: short fill weight, high fat in hamburger.)

Incident classification may change as current information dictates.

Class I complaints are immediately investigated to protect the public health. DHS officials and other state or federal agencies are advised as required. If it becomes apparent from investigation that products outside California are affected, the appropriate state and federal agencies are notified.

Class II complaints are investigated in a timely manner following the above guidelines. Appropriate DHS officials and other state or federal agencies are advised as needed.

Class III complaints are generally referred to the responsible firm for corrective action. The complaint is most often referred by telephone or letter, and FDB requests to be notified of the follow-up actions taken by the firm.

Complaints involving products manufactured out-of-state are coordinated with the appropriate federal agency (e.g., FDA, USDA, or CPSC) for follow-up with the manufacturer. Class I and II complaints are telephoned or FAXED to the federal agency immediately. Class III complaints are mailed to the agency. FDB has a MOU with FDA in which it is agreed that complaints and tampering incidents involving potential health hazards will be initially investigated by the agency which first received the complaint, with the other agency providing support as needed.

FDB recognizes that when referring complaints to an outside agency, that agency will need complete and accurate information for follow up. There are provisions within state law that permit the confidential referral of complaint information to appropriate agencies. FDB uses the FDB Consumer Product Complaint Investigation Form

(Appendix A) for referral of complaint information. At minimum, FDB includes the following with a complaint referral whenever possible:

Name, address (including zip code), and telephone number (including area code) of complainant.
A clear, brief description of the complaint, illness or injury.
A complete description of the product(s), including brand, product name, size, code(s) or lot number(s).
Name and location of store where purchased.
Product manufacturer's name and address.

FDB uses its statutory powers under the California Health and Safety Code including its authority to inspect, take samples, review records, and embargo to investigate complaints. To the extent possible, FDB solicits the cooperation of industry to resolve complaints but, when necessary, seeks legal action.

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Consumer Product Tampering Incident Investigation Protocol

Background

Tampering is the purposeful introduction of an object or chemical into a product that could injure the user and/or cause financial harm to the manufacturer, distributor, or retailer. An alleged tampering is a report that a product has been tampered with. The reporter may have done the tampering or have knowledge of an alleged tampering. A suspected tampering is a report that a product has indications of having been tampered with. In this case, the reporter may be the consumer.

An opened container does not necessarily indicate a tampering. An illness is not considered a result of tampering unless determined so by a physician or other health care provider or by competent investigation. A contaminant such as a fly or a metal screw that does not appear to be intentionally added is not a tampering.

Under California law it is a felony, punishable by imprisonment in a state prison for 2 to 5 years, to mingle any poison or harmful substance with a food, drink, medicine, or pharmaceutical product. The law also provides for imprisonment of any person who maliciously informs any other person that a poison or other harmful substance has been or will be placed in any food, drink, medicine, pharmaceutical product, or public water supply. The California HSC specifically prohibits the adulteration of foods, drugs, devices, and cosmetics. Federal law makes food tampering, whether actual or threatened, a felony with penalties of life imprisonment, and fines up to $100,000.

LHD/DHS Interaction

Reports of tampering involving consumer products, whether actual, alleged, or suspected, are to be immediately referred by LHDs to the nearest FDB office. Any consumer product samples involved are to be handled as little as possible to prevent masking of important evidence including fingerprints. FDB will investigate the incident and, as appropriate, alert the PD, FBI, and other agencies. FDB will first evaluate the information available, obtain and examine any samples of suspected products, and may take precautionary actions such as requesting the retailer to remove suspected products from store shelves pending results of examination. When tampering is indicated, FDB is responsible for management of the public health investigation, including elimination of the public health hazard from channels of trade, and notification of the public and various agencies. The PD or FBI is responsible for management of the criminal investigation to apprehend the perpetrator.

FDB will relay information to LHDs when there is reasonable likelihood that the alleged incident can cause injury or illness to consumers. FDB, in addition, may issue press releases when the incident is confirmed as having the potential for widespread health concern.

FDB may ask LHDs to assist in the investigation of some tampering incidents. (See Chapter 4.)

FDB Investigations

Reports of actual or alleged tampering received by FDB field offices are immediately reported by them to FDB headquarters (FDB-HQ). Contact is also made with the product's manufacturer(s), distributor(s), and/or retailer(s), and the appropriate PD or FBI office, to discuss a cooperative investigation and risk management strategy. In cases where products outside California may be involved, FDB-HQ also notifies the appropriate federal regulatory agency (FDA, USDA, CPSC, etc.).

When FDB receives reports of suspected tampering, in which there is no identified injury/illness to the consumer but where a product has indications of tampering, further evaluation of the incident is undertaken by the FDB field office to validate the incident as a tampering. Before notifying FDB-HQ or the PD, FDB investigators visually check the product carefully. Frequently what appear to be signs of tampering are actually manufacturing defects, or accidental damage during handling.

When tampering is confirmed, FDB acts rapidly to isolate the affected product and prevent its further distribution to the public.

FDB may ask LHDs to assist in the investigation and management of tampering incidents (See Chapter 4).

4

DHS Requests For LHD Assistance

Background

DHS may request LHD assistance in managing consumer product problems when LHD resources are needed to protect the public health. The requests may be to monitor recalls, perform surveillance during routine inspections, implement product remove-from-sale orders, or assist in tampering investigations. The following describes how such requests are to be made.

LHD/DHS Interaction

Recall Monitoring

Recall can be an effective method of removing from distribution, or otherwise preventing exposure to violative consumer products. DHS does not have the authority to order firms to recall a product or initiate a field correction, but can request that a firm do so as an alternative to an agency-initiated legal action by the courts to require the firm to do so. A DHS request that a firm recall a product is reserved for urgent situations where violative products present a risk of injury or gross deception of the public. DHS assists the involved firm in establishing an effective recall strategy (see Appendix 5).

In addition, DHS will notify by phone or FAX, all LHDs, which may be involved in the procedures even when the LHDs have not been requested to provide assistance.

A request by DHS for assistance in monitoring a recall will generally be made by FDB only for Class I or Class II recalls (see Appendix D) when FDB lacks sufficient resources to do the monitoring itself. This request will originate with the FDB Administrator, Section Chief, or FDB Branch Chief (or designee). Each LHD whose assistance is requested will be advised initially by phone, FAX, or e-mail with a follow-up letter. The request will provide the following information as available:

The class of the recall.

A clear statement of the action(s) requested of the LHD, including disposal procedures, if appropriate.

A complete description of the product including labeling, common name(s), size(s), manufacturer's name, code(s) or lot number(s), and any other means of identifying the product(s).

Reasons for the recall including applicable violations.

Estimated amount of product on the market and distribution information.

Reported or suspected health effects.

Name and telephone number of the FDB contact person.

Appropriate background information.

Surveillance

FDB may request surveillance assistance when specified violative consumer products are likely to be found offered for retail sale through outlets routinely inspected by LHDs. The request will be made for assistance to be provided only during the LHD's normal course of inspections or other activities. The request will provide the following information as available:

A clear statement of the action(s) requested of the LHD.

A complete description of the product including labeling, common name(s) size(s), manufacturer's name, code(s) or lot number(s), and any other means of identifying the product(s).

Reasons for the surveillance request including applicable violations.

Estimated amount of product on the market and distribution information.

Reported or suspected health effects.

Name and telephone number of the FDB contact person.

Appropriate background information.

Remove-from-sale orders

A remove-from-sale order will be issued by the Director of DHS only for Class I problems and then only when industry cannot or will not act as completely or as rapidly as the situation merits. If required, the order will empower LHDs to exercise specific pertinent authorities granted to DHS. Each LHD to which the order is directed will be advised initially by phone, FAX, or e-mail with a follow-up letter. The order will provide the same information as is provided under recall monitoring.

Tampering Investigations

Requests for LHD assistance in tampering investigations will originate from the Chief of FDB (or designee), the FDB Field Operations Chief, or an FDB Regional Administrator, and will generally be made only when additional resources are necessary to protect public health and safety. Each LHD whose assistance is requested will be advised initially by telephone, with follow-up by FAX or letter. The request will provide the following information:

A clear statement of the action(s) requested of the LHD, including disposal procedures, if appropriate.

Reasons for the requested action(s), including appropriate violations.

A complete description of the product including labeling, common name(s), size(s), manufacturer's name, code(s) or lot number(s), and any other means of identifying the product(s).

Estimated amount of product on the market and distribution information.

Reported or suspected health effects.

Name and telephone number of the FDB contact person.

Appropriate background information.

5

Removal of Products From The Marketplace

Background

Consumer products which are known to pose a risk to public health, or may reasonably be expected to pose a risk to public health, must be removed from the marketplace. Corrective action must be taken jointly by industry, and state and local health agencies.

Industry Actions

Industry may correct or mitigate consumer product problems by several methods:

Product recall

A voluntary action taken by industry, sometimes urged or recommended by governmental agencies, to remove from one or more levels of distribution a consumer product which presents public health risk or is otherwise in violation.

Product withdrawal

A voluntary action, taken by industry, to remove from one or more levels of distribution a consumer product which presents no public health risk or is otherwise not in violation. Examples include a product which is the wrong color shade or which bears a misaligned label.

Field correction

A voluntary action taken by industry to correct a consumer product problem in the field at one or more levels of distribution. Examples include product problems which can be corrected by a change in labeling or substitution of parts. Field correction is often used for medical devices. The term includes actions taken by industry for economic reasons to correct a problem which may not pose a public health risk or otherwise be in violation.

Media release

A voluntary action taken by industry to inform the public through the electronic and print media about an actual or potential consumer product problem.

Government Actions

Government may respond to industry's corrective action, if any is taken, or may take independent corrective action:

Remove-from-sale order
An action taken by the Director of DHS directing one or more LHDs to remove from the retail level of distribution a product which poses a significant public health risk (HSC § 100180).

Embargo
An action taken by DHS (or some LHDs which enforce the Sherman Law) at a particular place to prevent further sale of violative *foods, drugs, medical devices, tableware, or cosmetics* (HSC § 111860).

Quarantine
An action taken by DHS at a particular place to prevent further sale of violative *hazardous substances* (HSC § 108375).

Involuntary Destruction
An action taken by DHS at a particular place to condemn, destroy, or render unsalable by decharacterization any meat, meat products, seafood, poultry, vegetable, fruit, or other food which is unsound, which contains any filthy, decomposed or putrid substance, or which may be poisonous or deleterious to health or otherwise unsafe (HSC § 111890). This action is most often used during or following disasters such as floods, fires or earthquakes.

Impound (LHD)
An action taken by LHDs at a particular place to prevent further sale of violative foods (HSC § 113930).

Seizure and destruction
An action taken by CDFA at a particular place to prevent further sale of violative *meat and poultry products* (Ag. Code § 18873).

Impound (CDFA)
An action taken by CDFA at a particular place to prevent further sale of violative *milk and dairy products* (Ag. Code § 32731).

Seizure & Holding for up to 24 hours
An action taken by DPR at a particular place to prevent further sale of *produce* suspected of containing excessive pesticide residues (Ag. Code § 12601).

Seizure
An action taken by the U.S. Marshal's Office on behalf of FDA, after obtaining a court order, to prevent further sale of violative *foods, drugs, medical devices, tableware or cosmetics* (21 USC § 334).

Injunction

Any of the above agencies may request the court to issue a temporary or permanent **injunction** to prohibit further sale of *consumer products*.

Media Release

An action taken by any of the above agencies to inform the public through the electronic or print media about an actual or potential consumer product problem.

DHS Recall Strategy -- Management Guide

The Chief of FDB, or designee, shall be responsible for the decision to request a voluntary recall, and to classify the recall.

Class I Recalls

All products that fall within this category shall be recalled. Class I recalls shall:

Be made to the consumer/user level.

Have an announcement made to the public by either DHS and/or the responsible firm containing the following information:

- That the product in question is subject to a recall.
- That further distribution or use of any remaining product should cease immediately.
- Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
- Instructions regarding what to do with the product.
- Contents - a recall communication should be:

    - Concise;
    - Clearly identify the product, size, lot number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
    - Announced by the Department as soon as possible to FDB field offices, LHDs, FDA and other state and federal agencies;

Have effectiveness checks made to evaluate effectiveness of removal.

Management Action:

The Director of DHS shall be immediately notified by the FDB Chief (or designee)of all Class I recalls. An appropriate response plan including all actions required to resolve or mitigate the situation shall be prepared by FDB for the Director's approval.

The FDB Chief (or designee) shall plan and implement responsive action. The FDB Chief shall advise all local health officers and directors of environmental health of the issue, and keep them informed when new information becomes available. When appropriate, the FDB Chief shall coordinate the DHS Director's order which requires participation and action by local health agencies. The FDB Chief shall monitor all local

activities in response to the emergency action and coordinate the exchange of information and activities between DHS and the local agencies.

The FDB Chief shall coordinate with other state and federal agencies (i.e., CDFA, FDA, CPSC, etc.) which may have jurisdiction, responsibility or be affected. The FDB Chief shall coordinate sampling plans with laboratory support services and coordinate or advise other DHS agencies which may be required for support services or require information. The FDB Chief (or designee) shall work with the DHS Office of Public Affairs (OPA) for notification of media and participate in preparation of press releases for consumer alerts.

Local health agencies may be requested by the Director of DHS to take the following actions in retail establishments:

- Order retailers to remove products from sale.
- Monitor removal from sale actions pursuant to the DHS Director's orders.
- Embargo, quarantine, impound or monitor voluntary destruction of product. This may require more than one visit to assure product removal.

Class II Recalls

Products that pose a potential threat to consumer health and safety shall be recalled. Class II recalls include products that are violative due to filth contamination or are significantly misrepresented. Class II recalls shall:

Be made to the retail level.

Be publicly announced by DHS and/or the responsible firm if appropriate for public health and safety.

Have effectiveness checks made to evaluate adequacy of removal.

Management Action:

The DHS Director will be advised by the FDB Chief of the response plan to resolve or monitor the situation.

The FDB Chief will advise all health officers and directors of environmental health the issue(s) when appropriate coordination of the DHS Director's orders requires participation or information distribution.

Class II recalls may require the following participation of LHDs:

- Survey retail establishments to determine if product is being held for sale, has been removed, destroyed or returned to the distributor or manufacturer. If a remove-from-sale order has been issued, retail stock on the shelf may require embargo, quarantine, impound or destruction.

- Survey of retail establishments may be requested to be conducted by telephone, or may be requested as part of routine inspections as a monitoring program.

The FDB Chief (or designee) will coordinate with other state and federal agencies, and with the DHS Office of and Public Affairs (OPA) to prepare media and consumer information releases and responses.

Class III Recalls

Class III recalls shall:

Be made to the wholesale level.

Have effectiveness checks made to determine progress of reconditioning (e.g., relabeling, destruction) of violative products.

Management Action:

The FDB Chief (or designee) will manage any monitoring, product sampling and distribution of information to local health agencies, media, and public responses.

Class III recalls will be handled mainly as an information only situation. Local health officers and directors of environmental health will be advised when their jurisdiction is impacted, when there is need to respond to the public and media, and when other circumstances warrant distribution of information.

Actions Not Classified as Recalls

Withdrawal of products from distribution, when none of the products has left the direct control of the manufacturer or primary distributor, whether stored in their plant or in premises under their control, will not be classified as recalls. Effectiveness checks shall be made on the adequacy of such removals; however, the actions will not be placed on the public recall list.

Product withdrawals or field corrections when there are no violations or only minor violations that would not be subject to legal action under existing state laws and regulations will not be classified as recalls. No effectiveness checks will be made on the adequacy of such removals, and the actions will not be placed on the public recall list.

Effectiveness Checks Guide

The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, FAX, letters, or a combination thereof. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Department will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will conducted as follows:

Level A - 100% of the total number of consignees to be contacted;
Level B - Some percentage of the total number of consignees to be contacted. The percentage will be determined on a case-by-case basis, but will be greater than 10% and less than 100% of the total number of consignees;
Level C - 10% of the total number of consignees to be contacted;
Level D - 2% of the total number of consignees to be contacted; or
Level E - No effectiveness checks.

Appendix A - Reporting Forms

Consumer Product Complaint Investigation Form[1]

The consumer product complaint investigation form was developed to standardize statewide consumer complaint reporting. It includes a patient interview form to ensure that appropriate background information is collected for illness and injury investigations. It is recommended that LHDs use this form as a guide when referring non-food consumer product complaints, and non-illness/injury complaints involving commercially processed food to FDB; and when alerting FDB when the LHD investigation of a foodborne illness or injury implicates a commercially processed food, meat or poultry, a dairy product or produce.

Investigation of a Foodborne Outbreak

The LHD should send or FAX the Investigation of a Foodborne Outbreak form (CDC 52.13, Rev 9/83, or its successor) to DCDC after completing its epidemiologic investigation of a foodborne disease outbreak. An outbreak is defined as an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness, except that one case of botulism or chemical poisoning constitutes an outbreak. Completion of the Foodborne Outbreak Report form may take several days or weeks depending upon the logistics of the investigation and the resources available. Therefore, LHD's are asked to notify DCDC and FDB promptly (via phone, fax, e-mail) when a Foodborne Illness Investigation is initiated.

Pesticide Illness Report

Physicians are required (HSC § 105200) to report pesticide related illnesses to the local health officer, by telephone, within 24 hours. The local health officer should immediately notify the county agricultural commissioner and, within seven days, report each case to DPR and OEHHA using the Pesticide Illness Report Form (Form LAB-1000 (Rev. 11/87), or its successor). County health officials should be aware of these requirements when training staff and local physicians in the investigation of pesticide related occupational or foodborne illnesses.

Laboratory Analysis Request (LAR)

When the LHD consults a DHS laboratory prior to submitting a sample to that laboratory, the laboratory may ask that specific information or a specific form accompany the sample. If not, it is recommended that LHDs use the FDB Laboratory Analysis Request (LAR) form when submitting samples to the DHS laboratories for analysis.

Case History of Salmonellosis or Other Gastrointestinal Zoonoses

When the LHD investigation indicates salmonellosis or other gastrointestinal zoonoses, this form (8023-011) should be completed and returned to DHS. Copies can be obtained from the DHS Office of Statistics and Surveillance, (916) 327-7024.

CONSUMER PRODUCT COMPLAINT INVESTIGATION FORM (Page 1 of 3)

For Investigation of Food, Drug & other Consumer Product Complaints

Taken By: **Complaint ID:** **Phone:** _____

Date:

Reported By

Name: **Phone:** ( ) _____ - _____

Phone: ( ) _____ - _____

Agency:

Street:

City: **State:** **ZIP**

Product

Product Class (F-Food, D-Drug, M-Device, C-Cosmetic, H-Hazardous Substance, A-Art/Craft, T-Tableware, O-Other):

FDB Code:

Product: **UPC**:

Brand: **Product Code:**

Product Exp Date:

Size/Type of Container: **Import? Yes /** No

Where Purchased/served: **PURCHASE DATE:**

Street Address:

City: **State/Country:** **ZIP:**

Responsible Firm:

FDB Registration/license number: **Exp. Date:** **FDA CFN#:**

Street Address: **PHONE NUMBER:**

City: **State:** **ZIP**

Complaint/Problem Description:

PROBLEM CODE:

If there is an Illness/Injury involved, include Attachment A -- Patient Interview ***Illness/Injury Alleged:***

Supervisor Review **Action Indicated:**

By: Rank:

Notify:

CONSUMER PRODUCT COMPLAINT INVESTIGATION FORM (Page 2 of 3)

Refer To: FDA CDFA CPSC USDA DPR DCDC DEODC

LHD Other _____

Open Case Case # _____

Assign to: Due Date: _____

Collect Samples: _____

Submit Samples: FDL MDL FDA (Alameda) FDA (LA) Other _____

Instructions: _____

Follow-up/Actions Taken

DATE AND INITIAL ALL ENTRIES

FDB Complaint - Rev. 2.1 10\94

CONSUMER PRODUCT COMPLAINT INVESTIGATION FORM (Page 3 of 3)

Problem Summary (Complete after investigation)

Tampering User / consumer Design / Formulation Manufacturing No Problem Found

Misbranding (Describe) _____

Adulteration Other _____

Microbiological (describe) _____

Pesticide (describe) _____

Chemical (describe) _____

Insects / Filth (describe) _____

Other (describe) _____

Not Known

Date Closed: Final Ranking: _____

Comments: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

By: _____

FDB Complaint - Rev. 2.1 10\94

CONSUMER PRODUCT COMPLAINT INVESTIGATION FORM
ATTACHMENT A - PATIENT INTERVIEW (Page 1 of 2)

FOR EACH ILLNESS/INJURY, PROVIDE THE FOLLOWING (ATTACH ADDITIONAL SHEETS IF NEEDED):

Pt Name: _____

Sex: Age: Height: Weight:

Phone: Home ( ) - Work ( ) - _____

Date/Time of Exposure: Describe Exposure: _____

_____

_____

Symptoms	Onset Date/Time	Duration (hours)
Fever		
Chills		
Diarrhea		
Nausea		
Blurred Vision		
Vomiting		
Dizziness		
Cramps		
Other		

Hospitalization? Y / N Name/Location of Hospital: _____

Date: _____

Physician Diagnosis: _____

Physician Name: _____

Telephone: ( ) - Ext: _____

FDB Patient Interview - Rev. 2.1 10\94

ATTACHMENT A - PATIENT INTERVIEW (Page 2 of 2)

Laboratory Findings: _____

Private Laboratory State Laboratory Other _____

Patient Information Disclosure: Y / N

Comments: _____

FDB Patient Interview - Rev. 2.1 10\94

Investigation of a Foodborne Outbreak, CDC 52.13 rev. 9-89 two-sided form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333

CDC USE ONLY ☐☐☐☐ (1-4)

FORM APPROVED
OMB NO. 0920-0004

INVESTIGATION OF A FOODBORNE OUTBREAK

1. Where did the outbreak occur ?

State _____ (5-6) City or Town _____ County _____

2. Date of outbreak: (Date of onset 1st case)

_____
MO / DA / YR (7-12)

3. Indicate actual(s) or estimated number:

Persons exposed _____ (13-17)

Persons ill _____ (18-22)

Hospitalized _____ (23-27)

Fatal cases _____ (28-32)

4. History of Exposed Persons:

No. histories obtained _____ (33-35)

No. persons with symptoms _____ (36-38)

Nausea _____ (39-41) Diarrhea _____ (42-44)

Vomiting _____ (45-47) Fever _____ (48-50)

Cramps _____ (51-53) Other, specify _____ (54-75)

5. Incubation period (hours):

Shortest _____ (80-82) Longest _____ (84-87)

Approx. for majority _____ (88-91)

6. Duration of Illness (hours):

Shortest _____ (92-95) Longest _____ (96-99)

Approx. for majority _____ (101-104)

7. Food - specific attack rates:

Food Items Served	Number of persons who ATE specified food				Number who did NOT eat specified food			
	Ill	Not Ill	Total	Percent Ill	Ill	Not Ill	Total	Percent Ill

8. Vehicle responsible food item incriminated by epidemiological evidence: (105-106)

9. Manner in which incriminated food was marketed: (Check all Applicable)

	Yes 1	No 2		Yes 1	No 2	
(a) Food Industry			(e) Not Wrapped	☐	☐	(112)
Raw	☐	☐	(107)	Ordinary Wrapping	☐	☐	(113)
Processed	☐	☐	(108)	Canned	☐	☐	(114)
Home Produced				Canned—Vacuum Sealed	☐	☐	(115)
Raw	☐	☐	(109)	Other (specify)	☐	☐	(116)
Processed	☐	☐	(110)	_____			(117-129)
(b) Vending Machine	☐	☐	(111)	(f) Room Temperature	☐	☐	(130)
				Refrigerator	☐	☐	(131)
				Frozen	☐	☐	(132)
				Heated	☐	☐	(133)

If a commercial product, indicate brand name and lot number

_____ (134-150)

10. Place of Preparation of Contaminated Item: (151)

Restaurant	☐ 1
Delicatessen	☐ 2
Cafeteria	☐ 3
Private Home	☐ 4
Caterer	☐ 5
Institution:	
School	☐ 6
Church	☐ 7
Camp	☐ 8
Other, specify	☐ 9

_____ (152-171)

11. Place where eaten: (172)

Restaurant	☐ 1
Delicatessen	☐ 2
Cafeteria	☐ 3
Private Home	☐ 4
Picnic	☐ 5
Institution:	
School	☐ 6
Church	☐ 7
Camp	☐ 8
Other, specify	☐ 9

_____ (173-192)

This questionnaire is authorized by law (Public Health Service Act, 42 USC 241). Although response to the questions asked is voluntary, cooperation of the patient is necessary for the study and control of the disease. Public reporting burden for the collection of information is estimated to average 15 minutes per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to PHS Reports Clearance Officer, Rm 721-H, Humphrey Bg; 200 Independence Ave, SW, Washington, DC 20201; ATTN: PRA, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

CDC 52.13 REV. 9/89 (over)

LABORATORY FINDINGS (Include Negative Results)

12. Food specimens examined: (193)
Specify by "X" whether food examined was original (setup at time of outbreak) or check-up (prepared in similar manner but not involved in outbreak).

Item	Orig.	Check up	Findings Qualitative	Findings Quantitative
Example: beef	X		C. perfringens, Hobbs type 10	2×10^6/gm

13. Environmental specimens examined: (194)

Item	Findings
Example: meat grinder	C. perfringens, Hobbs Type 10

14. Specimens from patients examined (stool, vomitus, etc.): (195)

Item	No. Persons	Findings
Example: stool	11	C. perfringens, Hobbs Type 10

15. Specimens from food handlers (stool, lesions, etc.): (196)

Item	Findings
Example: lesion	C. perfringens, Hobbs Type 10

16. Factors contributing to outbreak (check all applicable):

	Yes 1	No 2	Unk.	
1. Improper storage or holding temperature	☐	☐	☐	(197)
2. Inadequate cooking	☐	☐	☐	(198)
3. Contaminated equipment or working surfaces	☐	☐	☐	(199)
4. Food obtained from unsafe source	☐	☐	☐	(200)
5. Poor personal hygiene of food handler	☐	☐	☐	(201)
6. Other, specify	☐	☐	☐	(202)

17. Etiology: (203-204)

Pathogen _____ Suspected ☐ 1 (205)
Chemical _____ Confirmed ☐ 2
Other _____ Unknown ☐ 3

18. Remarks: Briefly describe aspects of the investigation not covered above, such as unusual age or sex distribution; unusual circumstances leading to contamination of food, water, epidemic curve; etc. (Attach additional page if necessary)

(206-225)

Name of reporting agency: (226)

Investigating official: Date of Investigation:

NOTE: Epidemic and Laboratory Assistance for the investigation of a foodborne outbreak is available upon request by the State Health Department to the Centers for Disease control, Atlanta, Georgia 30333

To improve national surveillance, please send a copy of this report to:

Enteric Diseases Branch
Bacterial Diseases Division
Center for Infectious Diseases
Centers for Disease Control
Atlanta, Georgia 30333

Submitted copies should include as much information as possible, but the completion of every item is not required.

CDC 52.15 (back)
REV. 5/88

State of California -- Health and Welfare Agency Department of Health Services

PESTICIDE ILLNESS REPORT

PATIENT:
Name: Age: Sex: M F
Address: City: County:
Phone No.:( ) Social Security Number:

INJURY:
At Address: City: County:
Was Injury: [ ] 1 At Home [ ] 2 At Work -- agriculture [ ] 3 At Work -- nonagriculture [ ]4 Other Exposure
If at work: a) Employer's name and address:

b) Manager or Supervisor:

Date of Exposure: / / Time of Exposure: Date of Illness: / / Date of Death: / /

Is there reason to believe others were exposed? [ ] 1 No [ ] 2 Yes

PATIENT'S DESCRIPTION OF EXPOSURE:
Activity at time of exposure: [ ] 1 Applying Pesticides [ ] 2 Manufacturing Pesticides [ ] 3 Mixing Pesticides
[ ] 4 Entering Pesticide Areas [ ] 5 Disposing of Pesticides or their containers [ ] 6 Eating Contaminated Food
[ ] 7 Other Exposure (explain):

Name of Pesticide(s): Ingredients(s) of Pesticide(s):

Primary Route of Exposure: [ ] 1 Oral [ ] 2 Dermal [ ] 3 Eye [ ] Inhalation [ ] 5 Unknown

PHYSICIAN'S DESCRIPTION OF EXPOSURE:
Date first seen: / / Time first seen:
Major signs, symptoms, adverse reactions:

Hospitalized? [ ] 1 No [ ] 2 Yes If yes, hospital name: City:
Hospital phone: ( )
Emergency room only? [ ] 1 No [ ] 2 Yes
Physician's office only? [ ] 1 No [ ] 2 Yes
Physician (name and address):

Diagnostic studies ordered? [ ] 1 No [ ] 2 Yes If yes, which studies?

Brief description of incident (if female, indicate if pregnant):

AGENCY COMPLETING FORM:

Name/Agency/County:

Pesticide illness reporting is required by the California Health and Safety Code
Please complete as much information as possible and submit form promptly.

Form LAB-1000 (Rev. 11/87)

LABORATORY ANALYSIS REQUEST (LAR)

I.S. #	E #	FOR LABORATORY USE ONLY

Submit Sample To:

				L. S. #	Location
	Food & Drug Lab - Emeryville Food & Drug Lab - S. Calif.		Microbial Diseases Lab Other _____	From	Date/Time
FDB Notified of Results By				Assigned To	Date
Name		Date		Date Due	

SAMPLED BY	Date/Time Sampled
Name/Number	Agency/Office
Address	Telephone Number
Fax Number	Pager Number

PRODUCT INFORMATION	FDB Commodity Code	Lot/Code Number	Expiration/Pull Date

Product Description

Manufacturer/Distributor Name and Address

Label Information

Firm/Location Where Sampled

Amount of Sample Collected	Amount of Sample Submitted to Lab

Special Handling (Check One)		Freeze		Refrigerate		Fragile		Perishable		Other _____

Sampling Program Name (Check One) / Sampling Category (Check One)

	Food		Cosmetic		Other _____ _____		Emergency		Surveillance
	Drug		Haz. Subst.				Time Factor Compliance		Consumer
	Device		Fraud				Non Time Factor Compliance		Other _____

Analysis Requested

Reason for Analysis

Comments

APPROVAL INFORMATION	Date of Approval
FDB Regional Administrator	Via Phone By

Priority (Check one)		E		I		II		III	Date Due

Appendix B - Contact Persons, Addresses & Telephone/FAX Numbers

California Department of Health Services (DHS)

Office of Emergency Services
24-hour emergency telephone number: (916) 262-1621 or (916)845-8911

DHS Division of Communicable Disease Control (DCDC)
Duc Vugia, M.D., M.P.H., Chief
Disease Investigations and Surveillance Branch
2151 Berkeley Way, Room 708
Berkeley, CA 94704
Telephone: (510) 540-2566; FAX: (510) 540-2570

DHS Division of Environmental and Occupational Disease Control (DEODC)
Richard Krentzer, M.D., M.P.H., Chief
Environmental Health Investigations Branch
2151 Berkeley Way
Berkeley, CA 94704
Telephone: (510) 540-2115; FAX: (510) 540-2673

DHS Division of Food, Drug and Radiation Safety (DFDRS)
Larry Barrett, D.V.M., M.S, Chief
601 North Seventh Street MS-419
Sacramento, CA 95814
Telephone: (916) 324-3266; FAX (916) 323-4589

Food and Drug Branch (FDB)
James M. Waddell, Acting Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 324-3990; FAX: (916) 322-6326 email: jwaddell@dhs.ca.gov

FDB Food Safety Section -
James M. Waddell, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 324-3990; FAX: (916) 322-6326 email: jwaddell@dhs.ca.gov

FDB Food Safety Inspection Unit

Patrick Kennelly, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 322-7114; FAX: (916) 322-6326 email: pkennell@dhs.ca.gov

General Food Safety Team

Food and Drug Branch Northern California
Tony Munoz, Regional Administrator
6100 Paseo De San Antonio # 304
San Jose CA 95113
Telephone: (408) 277-1142; FAX: (408) 277-1141 email: amunoz@dhs.ca.gov

Food and Drug Branch Southern California
Prosy Delacruz, Regional Administrator
1449 West Temple Street, Room 224
Los Angeles, CA 90026
Telephone: (213) 580-5720; FAX (213) 580-5750 email: pdelacru@dhs.ca.gov

Emergency Response Unit
Jeff Farrar, D.V.M, M.P.H., Ph.D., Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 324-4000; FAX: (916) 322-6326 email: jfarrar@dhs.ca.gov

Seafood Safety Unit
Michael Hernandez, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 327-8037; FAX: (916) 322-6326 email: mhernan1@dhs.ca.gov

Retail Food Unit
Jeff Lineberry, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 327-6905; FAX: (916) 322-6326 email: jlineber@dhs.ca.gov

Food Safety Education & Training Unit
Consumer Complaint Program
Ingeborg B. Small, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 322-8443; FAX: (916) 322-6326 email: ismall@dhs.ca.gov

FDB Medical Device Safety Section
Christopher Wogee, Chief

601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 327-6961; FAX: (916) 322-6326 email: cwogee@dhs.ca.gov

FDB Medical Device Safety Unit
Barbara Moynier, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 327-6961; FAX: (916) 322-6326 email: bmoynier@dhs.ca.gov

FDB STAKE Unit
Dan Walsh, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 327-7329; FAX: (916) 322-6326 email: dwalsh@dhs.ca.gov

FDB Drug Safety Section
Susan Bond, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 327-6992; FAX: (916) 322-6326 email: sbond@dhs.ca.gov

FDB Drug Safety Unit
Glen Lawrence, Chief
601 North 7th Street, MS-357, Sacramento, CA 95814
P.O. Box 942732, Sacramento, CA 94234-7320
Telephone: (916) 327-6992: FAX: (916) 322-6326 email: glawren1@dhs.ca.gov

FDB Consumer Complaint Reporting 1(800) 495-3232

DHS Laboratories

The specific laboratory whose assistance is required must be consulted before any samples are submitted. The consultation must be between the local laboratory director and the designee of the state laboratory involved. The samples must be submitted via the nearest FDB field office. For this service, contact the respective Food and Drug Branch Administrator or Section Chief (pages 30-31).

Microbiological Support:

Microbial Diseases Laboratory Branch
2151 Berkeley Way
Berkeley, CA 94704-9980
Telephone: (510) 540-2242; FAX (510) 540-2374

Food and Drug Laboratory Support:

Food and Drug Laboratory Branch
5705 Hollis Street
Emeryville, CA 94608
Telephone: (510) 450-3941; FAX (510) 450-3027

California Department of Food and Agriculture

CDFA Chemistry Laboratory Services
3292 Meadowview Road
Sacramento, CA 95832
Telephone: (916) 262-1434; FAX (916) 262-1572

CDFA Milk and Dairy Foods Control Branch (MDFCB)
1220 N Street Room A-170
P.O. Box 942871
Sacramento, CA 94271-0001
Telephone: (916) 654-0773; FAX (916) 653-7512

Sacramento Region
2403 West Washington, Room 10
Stockton, CA 95203
Telephone: (209) 466-7186; FAX: (209) 466-1738

Fresno Region
2550 Mariposa Street, #3051
Fresno, CA 93721
Telephone: (209) 445-5506; FAX (209) 445-5509

Oakland Region
1515 Clay Street, Suite 803
Oakland, CA 94612
Telephone: (510) 622-4810; FAX: (510) 622-4808

Ontario Region
1910 South Archibald, Suite W
Ontario, CA 91761
Telephone: (909) 923-9929; FAX (909) 923-0359

CDFA Animal Health Branch (AHB)
1220 N Street Room A-107
P.O. Box 942871
Sacramento, CA 94271-0001
Telephone: (916) 654-1447; FAX (916) 653-2215

Redding District Office - District 1
2135 Akard Avenue, Room 8
Redding, CA 96001-2794
Telephone: (916) 225-2140; FAX (916) 225-2240

Modesto District Office - District 4
1620 North Carpenter Rd. - Suite D48
Modesto, CA 95351
Telephone: (209) 576-6330; FAX (209) 576-6198

Tulare District Office
18830 Road 112
Tulare, CA 93274
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Ontario, CA 91761
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Sacramento, CA 95814
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Central Area
5108 Clinton Way, Suite 127
Fresno, CA 93727
Telephone: (559) 233-7318

Southern Area
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California Environmental Protection Agency (CAL-EPA)

CAL-EPA Office of
Environmental Health Hazard Assessment (OEHHA)
301 Capital Mall , Second Floor
Sacramento, CA 95814
Telephone: (916) 324-7572; CALNET 8-454-7572; FAX (916) 327-1097

OEHHA's Pesticide and Environmental Toxicology Section
Hot Line: (916) 327-7319

PROPOSITION 65
Hot Line: (916) 445-6900

CAL-EPA Department of Pesticide Regulation (DPR)
Pesticide Enforcement Branch
1020 N Street, Room 300
Sacramento, CA 95814-5624
Telephone: (916) 445-3920; FAX (916) 445-3907

Federal Agencies

U.S. Food and Drug Administration (FDA)
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Consumer Complaint Officer
Telephone: (510) 337-6741; FAX (510) 337-6702

U.S. Food and Drug Administration (FDA)
Los Angeles District
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612
Consumer Complaint Officer
Telephone: (714) 798-7600; FAX (714)798-7725

FDA Seafood Hotline - (800) FDA-4010

FDA Medwatch (primarily for practitioner voluntary reporting of adverse effects from foods, drugs or medical devices)
5600 Fishers Lane
Rockville, MD 20852-9787
Telephone (800) FDA-1088; FAX(800) FDA-0178

U.S. Consumer Product Safety Commission (CPSC)

600 Harrison Street, Room 247
San Francisco, CA 94107
(415) 744-2966
Telephone (800) 638-2772 - Hotline for reporting dangerous products or product-related injuries.

U.S. Department of Agriculture (USDA)
The USDA has many offices located throughout the state. The local USDA office can be found in the local telephone directory under the federal government listings.
USDA Meat and Poultry Hotline
Telephone (800) 535-4555

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